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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,477	08/22/2006	Torsten Branderburger	05116835	1954

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EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
03/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No.	Applicant(s)	
	10/550,477	BRANDERBURGER ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Germany 103 13 760.2, filed on 27 March 2003 has been received.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 2, 10, 11, 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782).

5. Regarding claims 1 and 11, Strobel discloses a connector for packings containing medical liquids, particularly infusion, transfusion or enteral bags (col. 1, lines 5-10, 39-47, cols. 64-6, Fig. 1, system 1), comprising:

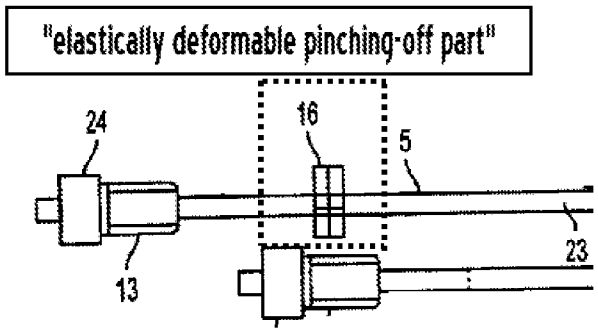
6. a connecting part with a passage which can accommodate a rod or a spike for filling or withdrawal of liquid (col. 4, lines 38-40, col. 5, lines 30-34, Fig. 1, delivery tube 5);

7. a closure part which can be fitted onto the connecting part and closes the passage in the connecting part (col. 5, lines 1-5, 21-29, Fig. 1, cap 24);

8. characterized in that the connecting part has an elastically deformable pinching-off part (portion of delivery tube 5; see annotated Fig. 1 of Strobel);

9. which re-assumes its original shape again after being pinched by a pinching device (col. 5, lines 62-67, Fig. 1, clamp 16 deforming delivery tube 5, which later re-assumes its original shape); and

10. a pinching-off part that merges into a base part which widens to both sides and which can be integrated in the packing (col. 5, lines 14-21, delivery tube 5 connected to opening 22, depicted as having a larger diameter and therefore widened to both sides).



Annotated Fig. 1 of Strobel; Michael (US 6723076)

11. Strobel discloses the invention substantially as claimed, see above. However, Strobel discloses only that delivery tube 5 is capable of transferring

fluid, and does not describe the specific cross-section shape. Therefore Strobel lacks a noncircular axial cross section as claimed [1, 11].

12. Imer discloses a resealable satchet for liquids (col. 1, lines 5-11, col. 2, lines 61-68, Fig. 1, satchet 1), comprising:

13. a connecting part (col. 3, lines 2-15, Fig. 1, opening strap 4);

14. with a passage (col. 3, lines 2-15, Fig. 1, outlet channel 3.1); and

15. a pinching-off part (col. 3, lines 20-27, Fig. 1, folding line 7);

16. that is designed as a tubular portion with a noncircular axial cross section that is different in two mutually perpendicular directions (col. 3, lines 28-31, portion of strap 4 near folding line 7 having substantially flat and noncircular axial cross section).

17. Imer solves the problem of containing and dispensing liquid from a bag with a resealable connection. Both Strobel and Imer dispense liquid through tubing attached to a bag, and use clamping mechanisms. Strobel applies clamp 16 to the outside of tube 5 (col. 5, lines 56-61), and Imer holds a folded portion of opening strap 4 within holding slit 6 (col. 3, lines 20-27).

18. Imer effectively clamps the portion of opening strap 4 within slit 6, to hold fluid within inner section 3 (col. 45, lines 12-18, especially lines 18-19, fold preventing leaks). A flat shape, or noncircular axial cross section prevents leaks through a clamped tube, since both surfaces of the tube contact each other when closed. In other words, a noncircular axial cross section is adapted for repeated clamping. One would be motivated to modify Strobel with the noncircular axial cross section as taught by Imer to hold fluid in a clamped state since Strobel calls for repeatedly clamping delivery tube

(col. 5, lines 56-67, selective coupling to injection system). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel as discussed with the noncircular axial cross section as taught by Imer in order to provide tubing or a connecting part adapted for clamping and resealing.

19. Regarding claims 2, 10, 12 and 20, Strobel discloses:

20. [2, 12] a closure part and connecting part secured with a snap fit (col. 5, lines 21-29, cap 24 for closing tube 5); and

21. [10, 20] a packing for medical liquids, particularly an infusion, transfusion or enteral bag, having at least one connector as claimed in claim 1 (col. 1, lines 5-10, bag for fluid medications or nutrients).

22. Claims 3, 5, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782), further in view of Fowles; Thomas A. et al. (US 4632267).

23. Regarding claims 3 and 13, Strobel and Imer disclose the invention substantially as claimed, see above. However, Strobel discloses that connectors 12 and 13 are luer or twist-type connectors (col. 4, lines 54-60, col. 5, lines 30-34), therefore Strobel and Imer lack a self-sealing membrane as claimed [3, 13].

24. Fowles discloses a connector for packings containing parenteral and peritoneal dialysis liquids (col. 1, lines 4-17, col. 2, lines 50-58, Figs. 1-3, port system); comprising:

25. a connecting part with a passage (col. 2, lines 50-58, Fig. 1, port 13 having lumen);

26. which can accommodate a rod or a spike for filling or withdrawal of liquid (col. 2, lines 66-3, Fig. 1, opening 22 for needle or other access means);

27. a closure part which can be fitted onto the connecting part and closes the passage in the connecting part (col. 2, lines 50-58, Fig. 1, closure 10);

28. [3, 13] a self- sealing membrane arranged between the connecting part and the closure part that can be pierced by the spike for withdrawal of the liquid (col. 2, lines 59-66, Fig. 1, partition wall 20 dividing tubular bore 18 into upper bore 19 and lower bore 21; Examiner interprets the wall 20 as substantially "between" a connecting part and closure part, since it is narrower than the lumens of both closure 10 and port 13. additionally, wall 20 is between closure 10 and the lower bore 21 of port 13).

29. Fowles provides a connecting part adapted to be repeatedly pierced with a needle. Both Strobel and Fowles provide a detachable cap (cap 24 of Strobel and closure 10 of Fowles) at the end of a connecting part (delivery tube 5 of Strobel and port 13 of Fowles). Withdrawal needles are commonly interchanged as Luer-type connectors. That is, systems that couple lumens with Luer connectors or a membrane and needle are commonly interchanged. Additionally, a needle-membrane system preserves sterility by preventing contaminants from entering the outlet of a bag.

30. One would be motivated to modify Strobel and Imer with the self-sealing membrane as taught by Fowles to preserve the contents of a dispensing bag since Strobel calls for an adapter that is connected intermittently and excludes contaminants

(col. 6, lines 43-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel and Imer as discussed by substituting a needle-membrane system of Fowles for the Luer connectors of Strobel in order to couple to dispensers commonly used in the art, while excluding contaminants.

31. Regarding claims 5 and 15, Strobel and Imer disclose the invention substantially as claimed, see above. However, Strobel and Imer lack an annular break zone as claimed [5, 15]. Fowles discloses:

32. a closure part having a cap-shaped bottom part which is adjoined via an annular break zone (col. 3, lines 49-58, Fig. 2, scored line 150);

33. by a top part that can be broken off (Fig. 3, detached portion of closure 110).

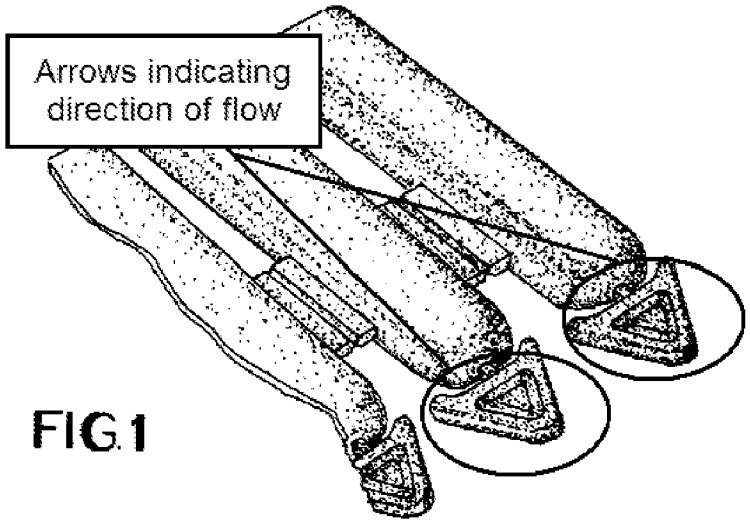
34. Here, Fowles seals a cap initially before a user can withdraw fluid from a container. That is, the container is tamper-evident since scored line 150 is broken when first removing fluid from the container. Afterwards, the user can reseal the connector by replacing closure 10 on port 12. Fowles shows whether a container has been opened, and prevents contaminants from reaching the exterior surface of a piercing membrane. One would be motivated to modify Strobel and Imer with the annular break zone and top part as taught by Fowles since Strobel calls for a sealing cap 24 placed on adapter 13.

35. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782) in view of Fowles; Thomas A. et al. (US 4632267), further in view of Burns (US 5494170).

36. Regarding claims 4 and 14, Strobel, Imer and Fowles disclose the invention as substantially claimed, see above. However, Strobel, Imer and Fowles lacks clamping with elastic deformation between a connecting part and a closure part as claimed [4, 14]. Burns discloses a closure part and connecting part secured with a snap fit (column 2, lines 61-67 and column 3, lines 13-23, Fig. 1, cam ring 4 and cooperating cam follower ring 16 forming snap-fit), further comprising a self-sealing membrane held clamped with elastic deformation between a connecting part and a closure part (column 2, lines 53-58 and Fig. 1, stopper 12 depicted as held between tube 1 and shield 11). Burns provides the advantage of simple construction in addition to multiple withdrawals. Additionally, holding a membrane with elastic deformation allows a different material to be used for a sealing membrane which may be more adaptable for repeated piercing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel, Imer and Fowles as discussed with the clamped, self-sealing membrane as taught by Burns in order to provide simple construction and multiple withdrawals.

37. Claims 6-8 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782) in view of Fowles; Thomas A. et al. (US 4632267), further in view of LeMarr et al. (US D456,507).

38. Regarding claims 6-8 and 16-18, Strobel, Imer and Fowles disclose the invention as substantially claimed, see above. However, Strobel, Imer and Fowles lack a flat grip piece and an arrow designed as a recess and/or as a raised structure as claimed [6-8, 16-18]. LeMarr discloses a nebulizer vial comprising a flat grip piece and an arrow designed as a recess and/or as a raised structure (see annotated Fig. 1 below). LeMarr provides the advantage of showing a user where fluid will exit a container when opened. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Strobel, Imer and Fowles as discussed with the arrow as taught by LeMarr in order to instruct a user.



Annotated Fig. 1 of LeMarr et al. (US D456507)

39. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel; Michael (US 6723076) in view of Imer; Rodney H. (US 5228782) in view of Fowles; Thomas A. et al. (US 4632267), further in view of Knierbein (US 6364143).

40. Regarding claims 9 and 19, Strobel, Imer and Fowles disclose the invention substantially as claimed, see above. However, Strobel, Imer and Fowles lack a boat

shape as claimed [9, 19]. Knierbein discloses a connector characterized in that the base part is designed in the shape of a boat (col. 3, lines 32-40 and Fig. 1, boat-shaped lower part 3 having boat-shape). Knierbein provides the advantage of effectively draining a liquid container. For example, a boat shape drains contents of a bag effectively when inverted. One would be motivated to modify Strobel, Imer and Fowles with the boat shape as taught by Knierbein to drain a liquid container effectively.

Response to Arguments

41. Applicant's arguments filed 15 January 2010 with respect to the rejection(s) of claim(s) 1-10 under 35 USC § 103 over Strobel, Imer, Fowles, LeMarr, Knierbein and Burns have been fully considered but are not persuasive. Therefore, the rejection is maintained.

42. Applicant notes that Strobel lacks an elastically deformable connecting part with a non-circular cross-section. Examiner instead cites Imer as teaching a non-circular cross-section as claimed.

43. Applicant reasons that Strobel also lacks a connecting part that can be pinched to prevent leakage after filling. Applicant finds that Strobel instead teaches a clamp for a delivery tube that prevents back flow through the delivery tube. Examiner interprets the language "a passage which can accommodate a rod or a spike for filling or withdrawal of liquid" and "an elastically deformable pinching-off part which re-assumes its original shape again after being pinched by a pinching device" as functional language. In the first case, delivery tube 5 is capable of accommodating a rod or spike, since it has a

lumen with a removable cap (col. 4, lines 54-60, Fig. 1, adapters 12, 13 are standard fittings with removable caps). In other words, each adapter 12, 13 has an accessible lumen capable of accommodating a rod or spike. In the second case, clamp 16 deforms delivery tube 5, and tube 5 later assumes its original shape to permit fluid flow. Therefore, adapter 13 and tubing 5 are capable of both functions as claimed.

44. Applicant asserts that Strobel teaches away from the present invention, since the user does not puncture or insert an object into the bag. Applicant finds no motivation to modify strobel by puncturing or inserting an object into the bag to withdraw liquids. Examiner notes that each of adapters 12, 13 are capable of accommodating an object, since they form a lumen covered with a removable cap.

45. Applicant submits that Imer fails to remedy the deficiencies of Strobel, namely a non-circular cross-section. Applicant finds that Imer instead requires folding rather than pinching. Examiner notes that folding a bag effectively pinches the flexible portion of Imer. For example, creasing or folding outlet channel 3.1 of Imer at folding line 7 urges the inner sides of channel 3.1 together to retain fluids within inner section 3. Similarly to clamp 16 of Strobel, Imer retains fluids within a tube by applying pressure to facing inner sides of a fluid channel.

46. Applicant contends that one of ordinary skill in the art would not look to Imer when developing an elastically deformable connecting part with a non-circular cross-section. Applicant reasons that both Strobel and Imer lack puncturing a seal, and are not combinable. Examiner notes that claims 1 and 11 do not require a puncturing" step or function, only the ability to "accommodate" a rod or a spike. That is, while the

specification suggests that the rod or spike puncture an element of the connector, this limitation does not appear in the claims.

Conclusion

47. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

48. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

49. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich
Tel 571-272-2590
Fax 571-273-2590

50. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

51. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

52. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
24 March 2010